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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/591,568

09/01/2006

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT

PAPER NUMBER

1624

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/591,568 | Applicant(s) BAKTHAVATCHALAM ET AL. | |
| | Examiner TAMTHOM N. TRUONG | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-17-07 (Preliminary Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47, 49-57, 60, 61, 68-74, 77-85, 89, 91, 92 and 94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47, 49-57, 60, 61, 68-74, 77-85, 89, 91, 92 and 94 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Lack of Unity

Applicant's preliminary amendment of 10-17-07 is acknowledged. Claims 1-47, 49-57, 60, 61, 68-74, 77-85, 89, 91, 92 and 94 are pending. Claims 48, 58, 59, 62-67, 75, 76, 86-88, 90, 93 and 95-96 are cancelled.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claim(s) 1-47, 49 and 50 (in part), drawn to compounds of the claimed formula(s), and pharmaceutical composition thereof, wherein V, X and Z represent N while Y represents CR₁, and R₃ does **not** form a ring with A₁. Further election of species and/or restriction will be required if this group is elected.

Group II: Claim(s) 1-5, 8-47, 49 and 50 (in part), drawn to the remaining compounds of the claimed formula(s)—not mentioned above, and pharmaceutical composition thereof. Further election of species and/or restriction will be required if this group is elected.

Group III: Claims 51-57, 60 and 61, drawn to a method for reducing calcium conductance of a cellular Capsaicin receptor. Further election of species and/or restriction will be required if this group is elected.

Group IV: Claims 68-71, drawn to a method for treating a condition responsive to Capsaicin receptor modulation. Further election of species and/or restriction will be required if this group is elected.

Group V: Claims 72-74 and 77-79, drawn to a method for treating pain. Further election of species and/or restriction will be required if this group is elected.

Group VI: Claims 80 and 81, drawn to a method for treating itching. Further election of species and/or restriction will be required if this group is elected.

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Group VII: Claims 82 and 83, drawn to a method for treating cough or hiccup. Further election of species and/or restriction will be required if this group is elected.

Group VIII: Claims 84 and 85, drawn to a method for treating urinary incontinence or overactive bladder. Further election of species and/or restriction will be required if this group is elected.

Group IX: Claim 89, drawn to a method for detecting the presence or absence of Capsaicin receptor. Further election of species and/or restriction will be required if this group is elected.

Group X: Claims 91, 92 and 94, drawn to a packaged pharmaceutical preparation. Further election of species and/or restriction will be required if this group is elected.

Inventions of Groups I - X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct from each other by the combination of variables V, X, Y and Z.

The inventions of Groups I - II share a common technical feature of a **fused pyrimidinyl or fused pyridyl** ring, which does not sufficiently define the invention, and is not a contribution to the art. It is the combination of variables V, X, Y and Z that defines the ring which in turn giving compounds of each group their unique physical, chemical properties and biological activities. Depending on what they represent, the claimed formula would have different structure. Thus, a reference anticipated or rendered obvious compounds of one group would not do so to those of other groups. Therefore, a separate search is required for each group.

The invention of Groups III – X are drawn to different methods of treating or preventing diseases related to Capsaicin receptor which relates to the other groups (I-II) as a combination-

subcombination, and requires additional search and examination beyond the scope of the claimed compound. A reference reading on the compounds would not necessarily read on the claimed method. Therefore, the search and examination for all 10 groups would impose a serious burden on the examiner in charge of this invention. Note, a preliminary search in EAST yields a total of 35,225 hits which clearly shows an overwhelming number of references for consideration.

Rejoinder Criteria: The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims **will be fully examined for patentability in accordance with 37 CFR 1.104**. Thus, to be allowable, **the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112**. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim

will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624

9-29-09